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In re
U S Patent No 4,103,001

Decision on Application
for Interim Extension of Patent
Term Under 35 U S C § 156(d)(5)

This is in response to the request for reconsideration, filed September 27, 1996, and supplemented December 11, 1996

The request for reconsideration is granted to the extent that the decision to deny interim patent term extension has been reconsidered, but the application for interim extension is again DENIED

BACKGROUND

An application for interim extension of the patent term of U S Patent No 4,103,001, under 35 U S C § 156(d)(5), was filed in the United States Patent and Trademark Office on August 2, 1996, and supplemented on August 14, 1996 Interim extension is sought based upon the premarket review under § 510(k) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a medical device known by the trade name SPORICIDIN Cold Sterilizing Solution

The application for interim extension was denied in a decision dated August 27, 1996 On September 27, 1996, applicant requested reconsideration, arguing that bills pending at the time before Congress directed the Commissioner of the PTO perform his duties in an equitable manner, and that granting an interim extension of the term of the above-identified patent based upon FDA's regulatory review would be compatible with this mandate A supplemental memorandum to the request for reconsideration, filed December 11, 1996, argues that the regulatory review under section 510(k) is related to and included in review under section 515 Applicant also states that most 510(k) regulatory reviews are completed within 90 days, but the regulatory review of SPORICIDIN has taken over five years

On November 7, 1996, a letter was sent to the Food and Drug Administration (FDA), requesting input on the request for reconsideration In reply, on December 23, 1998, FDA explained that the decision to deny the application for interim patent term extension was proper because the medical device SPORICIDIN was subject to regulatory review under section 510(k) of the FFDCA and, therefore, has not been subject to a regulatory review period as defined in 35 U S C § 156 FDA included copies of several PTO decisions consistent with this decision, including

one decision in which regulatory review began under section 515 and concluded with clearance of the product under section 510(k) On January 14, 1999, a supplemental letter was mailed by FDA, explaining that SPORICIDIN has not received permission under section 510(k) of the FFDCA

DISCUSSION

The Commissioner does not have authority to grant an extension of the term of the patent absent a statutory basis therefor A patent may be eligible for interim extension if "the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect" and "[i]f the Commissioner determines that, except for permission to market the product commercially, the patent would be eligible for patent term extension under this section " 35 U S C §§ 156(d)(5)(A) and (B)

The product "SPORICIDIN " is a medical device For a medical device, § 156(g)(3)(B) provides

> (3)(B) The regulatory review period for a medical device is the sum of -
> (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
> (ii) the period beginning on the date an application was originally submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6)

The reference to section 515(f) is a reference to section 515 of the FFDCA See 35 U S C § 156(f)(4)(B)

Under the terms of subsections 156 (a)(4) and 156 (g)(3)(B), the regulatory review of a medical device is defined only as a regulatory review which is conducted under section 515 of the FFDCA and therefore to the exclusion of regulatory review conducted under section 510(k) of the FFDCA Congress, by making specific reference to section 515 and not section 510(k) intended only 515 reviews of medical devices to give rise to eligibility for patent term extension Accordingly, the regulatory review period for SPORICIDIN under section 510(k) is not a "regulatory review period" which gives rise to eligibility for patent term extension under 35 U S C § 156(a) In re Nitinol Medical Technologies Inc , 17 USPQ2d 1492 (Comm'r Pat & Tm 1990) Regulatory review under section 510(k) is not regulatory review under section 515, and cannot result in approval of a product under section 515 See In re Cordis Corporation, U S Patent No 4,776,838, August 23, 1994 (attached to FDA's reply dated December 23, 1998)

Furthermore, subsection 156(d)(5)(A) provides that it is only when a regulatory review period described in section (g) extends beyond the expiration date of the patent that a patent may be eligible for patent term extension As set forth above, a regulatory review period conducted under section 510(k) is not a regulatory review period described in section (g) Accordingly, a patent is not eligible for interim extension if the regulatory review period was conducted under section 510(k)

Even if applicant's argument that the regulatory review of SPORICIDIN could be considered as having been under section 515 of the FFDCA and therefore a regulatory review as defined by 35 U S C § 156(g), the patent would still not be eligible for interim extension because a Premarketing Approval application (PMA) was never filed [1] 35 U.S.C 156(d)(5)(A), by requiring that the period described in section 156(g)(3)(B)(ii) have begun for a product, requires that the PMA be filed before the application for interim extension was filed Since the PMA was never filed,[2] the approval phase had not begun when the application for interim extension was filed, and the patent is not eligible for interim extension

As an aside, it is noted that, had applicant been eligible for interim extension, the interim extension would have extended the term of the patent from August 30, 1996, the original expiration date of the patent, until August 30, 1997 Since the product was not approved for commercial use or sale under section 515 of the FFDCA before August 30, 1997, and since no subsequent request for interim extension was filed in the period beginning 60 days before August 30, 1997 and ending 30 days before August 30, 1997 as required by 35 U S C § 156(d)(5)(C), even if the request for interim extension should have been granted, the patent cannot now be extended past August 30, 1997 Had an extension been improperly granted, it would have been vacated *ab initio* once the error in granting the extension was discovered See In re Reckitt & Colman Products Ltd , 230 USPQ 369, 372 (Comm'r Pat & Tm 1986)

DECISION

Under the circumstances of this application, for the reasons set forth above, and in the decision denying the application for patent term extension, mailed August 27, 1996, it is held that, notwithstanding any equities of the situation, U S Patent No 4,103,001 is not eligible for interim extension of the patent term under 35 U S C § 156 SPORICIDIN has not been subject to a regulatory review period within the meaning of 35 U S C §§ 156(a)(4) and (d)(5) as defined in

[1]21 U S C § 360c(c)(1) describes the requirements for an application for premarket approval

[2]See, e g , the December 11, 1996 Request for Reconsideration, Attachment D, a letter from FDA dated May 9, 1996, which suggests the filing of a PMA, after clinical investigations have been completed

35 U S C § 156(g)(3)(B), and the regulatory review period defined in 35 U S C § 156(g)(3)(B)(ii) has not begun for the product SPORICIDIN Accordingly, the application for interim extension of the patent term is again denied

Stephen G Kunin
Deputy Assistant Commissioner
for Patent Policy and Projects

cc RONALD L WILSON, DIRECTOR
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